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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-15-15DA]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the

agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Improving the Impact of Laboratory Practice Guidelines (LPGs): A New Paradigm for Metrics- American Society for Microbiology – NEW – Center for Surveillance, Epidemiology and Laboratory

Services (CSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention is funding three 5-year projects collectively entitled "Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics". An "LPG" is defined as written recommendations for voluntary, standardized approaches for medical laboratory testing that takes into account processes for test selection, sample procurement and processing, analytical methods, and results reporting for effective diagnosis and management of disease and health conditions. LPGs may be disseminated to, and used by, laboratorians and clinicians to assist with test selection and test result interpretation. The overall purpose of these cooperative agreements is to increase the effectiveness of LPGs by defining measures and collecting information to inform better LPG creation, revision, dissemination, promotion, uptake and impact on clinical testing and public health.

The project will explore how these processes and their impediments and facilitators differ among various intended users of LPGs. Through this demonstration project, CDC seeks to understand how to customize LPG creation and promotion to better

serve these intended users of LPGs. An important goal is to help organizations that sponsor the development of LPGs create a sustainable approach for continuous quality improvement to evaluate and improve an LPG's impact through better collection of information.

The CDC selected three organizations that currently create and disseminate LPGs to support activities under a cooperative agreement funding mechanism to improve the impact of their LPGs. The American Society for Microbiology (ASM), the Clinical and Laboratory Standards Institute, and the College of American Pathologists, will each use their LPGs as models to better understand how to improve uptake and impact of these and future LPGs. Only the ASM submission will be described in this notice.

The ASM project will address four LPGs that are important to clinical testing and have a high public health impact: reducing blood culture contamination (BCC), rapid diagnosis of blood stream infections (BSI), proper collection and transport of urine (UT), and microbiological practices to improve the diagnosis and management of patients with *Clostridium difficile* (*C. difficile*) infection (CDI). The BCC LPG was published and it includes recommendations for the use of: 1) venipuncture over catheters as the preferred technique for sample collection in a

clinical setting, and 2) phlebotomy teams over non-phlebotomist staff for collecting blood for culture. The BSI report examines the effectiveness of rapid diagnostic tests to promote more accurate and timely administration of targeted antibiotic therapy for patients with bloodstream infections. This report will be published and recommendations will be developed based on additional information collected. Practices related to the collection, storage and preservation of urine for microbiological culture that improve the diagnosis and management of patients with urinary tract infections were analyzed and approved recommendations will be published. Microbiological practices related to improving diagnosis and management of patients with *C. difficile* infection will be collected and analyzed, and recommendations will also be developed and published.

The intended respondents of ASM's surveys will include microbiology supervisors, laboratory directors, laboratory managers, and medical technologists. For this request for OMB approval of a new information collection, we will be requesting approval to collect baseline and post-dissemination information for the BCC LPG. Because the BSI, UT and CDI reports are not yet published, ASM will conduct a baseline survey to determine current practices prior to dissemination of the LPGs.

On behalf of the ASM and the CDC, the Laboratory Response Network (LRN), which was founded by the CDC, will recruit laboratories that perform the kinds of testing affected by these LPGs to take the surveys. Messages regarding ASM surveys will be worded as an invitation, not as a coercive request. Some states may opt not to recruit LRN laboratory participation, but because the issues are important to clinical and public health, we expect good participation by most states. This mechanism will assure the best response rate of all the options we considered.

The CDC LRN Coordinator will email a letter to the Laboratory Director of the LRN Reference Laboratories, (i.e., 50 State Public Health Laboratories, the New York City Public Health Laboratory and the Los Angeles County Public Health Laboratory). These 52 LRN Reference Laboratory Directors will be asked to then email the sentinel laboratories, which include hospital and independent laboratories, in their states, and provide a hyperlink to access the survey tool on-line. SurveyMonkey® will host the online survey and be used as the information collection instrument and responses will be collected and maintained by ASM.

We anticipate that approximately 4,200 sentinel laboratories will be contacted and asked to complete the survey on-line. ASM anticipates achieving an 80% response rate with their information collections, or 3,360 out of approximately 4,200 aggregate responses for each of the five different surveys.

In addition, the ASM will also recruit, by emailing a letter containing the SurveyMonkey® hyperlinks for the five surveys to each of their ClinMicroNet and DivCNet listervs inviting ~828 and ~1470 subscribers (comprised of laboratory directors as well as medical technologists in a 99%:1% and 60%:40%), respectively, to take each of the five SurveyMonkey® surveys. Moreover, the ASM will email the same letter containing the SurveyMonkey® hyperlinks for the 5 surveys to ~1453 *ASM Clinical Microbiology Issues Update* newsletter subscribers, which include microbiology supervisors, laboratory directors, laboratory managers, and medical technologists in a 25 percent:25 percent: 25 percent: 25 percent ratio, to invite them to participate.

For burden calculations, respondents will include microbiology supervisors, laboratory directors, laboratory managers, and medical technologists. According to ASM, the

burden hours per respondent who will be invited to participate in each of the BCC baseline and post-dissemination surveys will not exceed 35 minutes and each of the BSI, UT and CDI baseline surveys will be 20 minutes. This time frame was specified based on ASM's previous experiences conducting laboratory surveys. Each survey was pilot tested with 9 or fewer respondents before dissemination.

The total estimated annualized burden hours for this collection is 17,225. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)
Microbiology Supervisors	BCC-baseline	2,463	1	35/60
	BCC-post	2,463	1	35/60
	BSI-baseline	2,463	1	20/60
	UT-baseline	2,463	1	20/60
	CDI-baseline	2,463	1	20/60
Laboratory Directors	BCC-baseline	3,115	1	35/60
	BCC-post	3,115	1	35/60
	BSI-baseline	3,115	1	20/60
	UT-baseline	3,115	1	20/60
	CDI-baseline	3,115	1	20/60
Laboratory	BCC-baseline	1,413	1	35/60
	BCC-post	1,413	1	35/60

Managers	BSI-baseline	1,413	1	20/60
	UT-baseline	1,413	1	20/60
	CDI-baseline	1,413	1	20/60
Medical Technologists	BCC-baseline	960	1	35/60
	BCC-post	960	1	35/60
	BSI-baseline	960	1	20/60
	UT-baseline	960	1	20/60
	CDI-baseline	960	1	20/60

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